



PATENT
Attorney Docket No. MEE-005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Adamis et al.
SERIAL NO.: 09/478,099 GROUP NO.: 1632
FILING DATE: January 5, 2000 EXAMINER: Anne Marie Falk
TITLE: Delivery to the Retina and Choroid

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

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- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

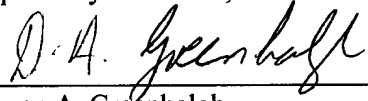
As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Date: September 19, 2003
Reg. No. 38,678

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Respectfully submitted,



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FORM PTO - 1449				ATTORNEY DOCKET NO.: MEE-005					
INFORMATION DISCLOSURE STATEMENT				APPLICANT(S): Adamis et al.					
				SERIAL NO.: 09/478,099					
				FILING DATE: January 5, 2000 GROUP: 1632					
U.S. PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE		
	A98	5,770,580	6/23/98	Ledley et al.	514	44			
	A99	5,792,751	8/11/98	Ledley et al.	514	44			
FOREIGN PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B13	97/15330	5/1/97	WO					
	B14	97/37542	10/16/97	WO					
OTHER ART, JOURNAL ARTICLES, ETC.									
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)								
	C9	✓ "Advances in CMV Management: Fomivirsen (Vitravene®) Approved" <u>PI Perspective</u> (1998) 26: 7.							
	C10	✓ Henry <i>et al.</i> "Antiviral Activity and Ocular Kinetics of Antisense Oligonucleotides Designed to Inhibit CMV Replication" <u>Invest. Ophthalmol. Vis. Sci.</u> (2001) 42(11): 2646-2651.							
	C11	Leeds <i>et al.</i> "Pharmacokinetics of a Potential Human Cytomegalovirus Therapeutic, a Phosphorothioate Oligonucleotide, After Intravitreal Injection in the Rabbit" <u>Drug Metab. and Disposition</u> (1997) 25(8): 921-926.							
	C12	de Smet <i>et al.</i> "Fomivirsen - a Phosphorothioate Oligonucleotide for the Treatment of CMV Retinitis" <u>Ocular Immunology and Inflammation</u> (1999) 7(3-4): 189-198.							
	C13	"Fomivirsen Approved for CMV Retinitis: First Antisense Drug" <u>AIDS Treat News</u> (1998) 302: 7							
	C14	"New CMV Drug Won't Replace Other Therapies" <u>AIDS Alert</u> (1998) 124-126.							
	C15	Roehr "Fomivirsen Approved for CMV Retinitis" <u>J. Int'l. Assoc. of Physicians in AIDS Care</u> (1998) 14-16.							
	C16	Robinson <i>et al.</i> "Oligonucleotides Inhibit Retinal Neovascularization in a Murine Model of Proliferative Retinopathy" <u>Proc. Natl. Acad. Sci. USA</u> (1996) 4851-4856.							
EXAMINER					DATE CONSIDERED				



SHEET 2 OF 2

FORM PTO - 1449		ATTORNEY DOCKET NO.: MEE-005	
INFORMATION DISCLOSURE STATEMENT		APPLICANT(S): Adamis et al.	
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OTHER ART, JOURNAL ARTICLES, ETC.			
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
	C17	Bhisitkul <i>et al.</i> "Antisense Oligonucleotides Against Vascular Endothelial Growth Factor in a Non-Human Primate Model of Ocular Angiogenesis" <u>Invest. Ophthalmol. Vis. Sci.</u> (1998) 39(4) Abstract.	
	C18	Carrasquillo <i>et al.</i> "Controlled Delivery of the Anti-VEGF Aptamer EYE001 with Poly(lactic-co-glycolic) Acid Microspheres" <u>Invest. Ophthalmol. Vis. Sci.</u> (2003) 44(1): 290-299.	
	C19	Henry <i>et al.</i> "Antiviral Activity and Ocular Kinetics of Antisense Oligonucleotides Designed to Inhibit CMV Replication" <u>Invest. Ophthalmol. Vis. Sci.</u> (2001) 42(11): 2646-2651.	
	C20	Masuda <i>et al.</i> "Gene Transfer with Liposomes to the Intraocular Tissues by Different Routes of Administration" <u>Invest. Ophthalmol. Vis. Sci.</u> (1996) 37(9): 1914-1920.	
	C21	Tiansen <i>et al.</i> "Phenotype Correction in Retinal Pigment Epithelium in Murine Mucopolysaccharidosis VII by Adenovirus-mediated Gene Transfer" <u>Proc. Natl. Acad. Sci. USA</u> (1995) 92: 7700-7704.	
	C22	Mashhour <i>et al.</i> "In vivo Adenovirus-mediated Gene Transfer into Ocular Tissues" <u>Gene Therapy</u> (1994) 1: 122-126.	
	C23	Tanelian <i>et al.</i> "Controlled Gene Gun Delivery and Expression of DNA Within the Cornea" <u>BioTechniques</u> (1997) 23(3): 484-488.	
EXAMINER		DATE CONSIDERED	